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DEPARTMENT OF HEALTH & HUMAN SERVICES

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-26

May 3, 2002

Mr. Dieter Pape, CEO
Morey's Seafood International, LLC
701 Decatur Avenue
Golden Valley, MN 55427

Dear Mr. Pape:

On September 21st through 24th, 2001 the Food and Drug Administration (FDA) conducted an inspection of your facility located at 12301 Conant, Detroit, MI. The inspection was conducted to determine compliance with the FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulation (21 CFR 123) and the current Good Manufacturing Practice requirements for foods (GMP) (21 CFR 110).

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. These deviations, some of which were previously brought to your attention, cause your fresh mahi mahi to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's homepage www.fda.gov.

These deviations were as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for histamine producers lists a critical limit of "temp. not more than [redacted] at the receiving critical control point that is not adequate to control the food safety hazard histamine formation. Because of the potential for temperature abuse during transit, adequate control consists of continuous monitoring of air or product temperature during transit or checking for adequacy of ice or coolant at receipt.

2. You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6 (b). However, your firm did not record monitoring observations at the receiving critical control point to control histamine information as listed in your HACCP plan for histamine producers. There was no documentation at the receiving step for 3 of 12 lots reviewed for fresh mahi mahi handled by your firm, (lots 8/6/01, 8/13/01 and 9/6/01) on that same day.

3. You must have a critical limit that must be met in order to comply with 21 CFR 123.6(c)(3). However, when our investigator pointed out that your cooler temperature rose above the critical limit of [redacted] your firm indicated that the product is also iced so no corrective action would be required. If you are using a critical limit in addition to or instead of "temp. not more than [redacted] that critical limit should be listed along with the appropriate monitoring procedures, frequencies and record keeping.

4. You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6 (b). However, your firm did not follow the monitoring frequency of recording temperatures of the north and south cooler three (3) times per day at the storage critical control point listed in your HACCP plan for histamine producers. Our investigator documented that these coolers were monitored only two (2) times on 06/18/02.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

We also note that your Cooler Temperature Log states "Critical Limit [redacted] This should be changed to reflect the correct Critical Limit of [redacted] This would prevent an unsuspecting employee from recording [redacted] on the Log, and not realizing that he/she must take corrective action.

Your written reply should be directed to David M. Kaszubski, Director Compliance Branch, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone (313) 226-6260 ext. 185.

Sincerely,

Joann M. Givens
District Director
Detroit District